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VLADIMIR S. GRNJA, M.D. JOEL A. SCHNEIDER, M.D., F.A.C.R.

February 25, 2000

Docket No. 99D-4910, Dockets Management Branch
Division of Management Systems & Policy
Office of Human Resources & Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)

To Whom It May Concern:

It seems that the new MQSA regulation 900.12 (B) (8) (I) requires that each mammography system have a fine adjustment compression control operable from both sides of the patient. In addition to the foot compression pedal the amount of change in compression of a patient by using a hand adjustment is of no clinical value. We have five mammography machines which are FDA certified and two of these machines do not have this hand operated fine tune knob. If this log goes into effect it would be an undue financial burden to replace these two machines.

I strongly oppose the change in the FDA requirement.

Very Truly Yours,

JOEL A. SCHNEIDER, M.D., F.A.C.R.

JS/A~

CC: Mary E. Swain, M.D.

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99D-4910

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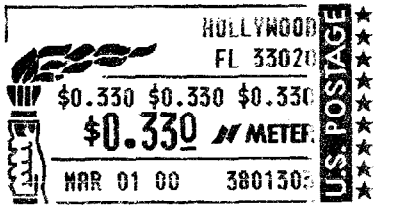
REPORTS



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Dockets management Branch/Systems + Policy
Div. of Human Resources + Management
Food + Drug Adm.
5630 Fishers Lane Rm 1061 (HFA-305)
Rockville MD 20852

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